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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,945	01/30/2002	Thomas Hermann	215482US0X	5458

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EXAMINER	
KERR, KATHLEEN M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,945	HERMANN ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

1. Claims 1-38 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-6, 10-22, 27 and 42-45, drawn to polynucleotides encoding OtsA transcriptional regulator protein and related products and methods, classified in class 435, subclass 69.1.

II. Claims 7-8 and 25-26, drawn to methods of making a polynucleotide encoding OtsA, classified in class 435, subclass 6.

III. Claims 9 and 23-24, drawn to methods of screening for a polynucleotide encoding OtsA, classified in class 435, subclass 193.

IV. Claims 28-31, drawn to Coryneform bacteria with an attenuated OtsA gene, classified in class 435, subclass 252.1.

V. Claims 32-39, drawn to methods of making amino acids using bacterial host cells with an attenuated OtsA gene, classified in class 435, subclass 106.

VI. Claim 40-41, drawn to the OtsA polypeptide, classified in class 435, subclass 193.

3. The inventions are distinct, each from the other because of the following reasons:

Group I is related to Group II because the methods of Group II use a fragment of the polynucleotides of Group I, thus related as product and process of use. The inventions can be

shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product can be used for a materially different process of using the product, such as in the recombinant production of the encoded enzyme. Thus, Group I is patentably distinct from Group II. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related to Groups III and V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product can be used for a materially different process of using the product, such as in the recombinant production of the encoded enzyme. Thus, Group I is patentably distinct from Group III and V. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related to the bacteria of Group IV because the cells lack the gene described in Group I. However, they are distinct inventions because while Group I is drawn to the presence of the gene, Group IV is drawn to the absence. Thus, Groups I and IV have distinct structures and function. Thus, Group I is patentably distinct from Group IV. Because these inventions are

distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Group I is related to the protein of Group VI by virtue of the fact that the DNA encodes the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, they are distinct inventions because they are wholly different in structure and function. Moreover, the protein product can be made by other and materially distinct processes, such as purification from a natural source; and the DNA product can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, Groups I and VI are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Group II are related to the methods of Group III by virtue of both methods using the OtsA polynucleotide. However, these methods are distinct because they use wholly different reagents and wholly different method steps to produce wholly distinct products. Moreover, the methods of Group II do not require the full length of the OtsA gene, and the methods of Group III require protein expression and activity assay steps. Thus, Groups II and III are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups II and III are related to the bacteria of Group IV because the cells lack the gene, which is used in the methods of Group III and a fragment of which is used in the methods of

Group II. They are distinct inventions because while Groups II and III require the use of products drawn to the presence of the gene or a fragment thereof, Group IV is drawn to products in the absence of the gene. Thus, Groups II-III and IV have or use products that have distinct structures and function. Thus, Groups II-III are patentably distinct from Group IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups II and III are related to the methods of Group V by virtue of the polynucleotides used in the methods of Groups II-III and absent in the methods of Group V. Due to the presence or absence of the OtsA gene, the products used in the methods are wholly distinct having distinct structures and functions. Thus, the methods practice distinct method steps. Moreover, the methods of Group V produce wholly distinct products from those of Groups II and III. Thus, Groups II and III are patentably distinct from Group V.

Groups II and III are related to Group VI by virtue of the OtsA polynucleotide used in the methods since it encodes the polypeptide. However, the polypeptide is neither used nor produced in the claimed methods. Thus, Groups II and III are patentably distinct from Group VI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group VI based on a distinct search of either nucleotide sequences or protein sequences in both sequence databases and text databases, restriction for examination purposes as indicated is proper.

Groups IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the products can be used in a materially different process of using the product, such as in a cell system screening for OtsA protein activity. This method makes a wholly distinct product from that of Group V using wholly different method steps. Thus, Groups IV and V are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group VI is related to the bacteria of Group IV because the cells lack the gene that encodes the proteins of Group VI. However, they are distinct inventions because while Group VI is drawn to protein, Group IV is drawn products in the absence of the gene (and the protein). Thus, Groups VI and IV have distinct structures and function. Thus, Group VI is patentably distinct from Group IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group V is related to the proteins of Group VI because the cells used in the methods of Group V lack the gene, which encodes the protein of Group VI. They are distinct inventions because while Group VI requires the products drawn to the presence of the protein, Group V is drawn to methods using products in the absence of the encoding gene. Thus, Groups V and VI have or use products that have distinct structures and function. Thus, Group V is patentably

distinct from Group VI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

4. The Examiner notes that if product claims in Group I are found directed to an allowable product, then process claims in Group III, which are directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

5. A telephone call was made to Daniel Pereira on October 1, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. A complete response to the instant Office action must include an election of invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
October 1, 2003